C13 wherein the polypeptide which prevents or lessens the severity of *Chlamydia* infection in the immunized mouse compared to a non-immunized control mouse is identified.

REMARKS

I. Amendments

The claims have been amended to remove non-elected subject matter and to replace indefinite articles with definite articles for further clarity. The phrase "according to" has also been replaced with "of" for consistency throughout the claims.

Because these amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Restriction

In response to the Restriction Requirement mailed on April 28, 2003, Applicants hereby elect the claims of Group 11 (claims 1-19, 25 and 38(a)), drawn to nucleic acids, vectors, host cells, and a method of producing the polypeptide CPN100638 (SEQ ID NOs: 5, 6 and 14), fragments and compositions thereof, for prosecution in the subject application, **with traverse**.

In response to the unity-of-invention requirement, Applicants elect the invention relating to SEQ ID NOs: 5, 6 and 14 (nucleic acid and amino acid sequences of the polypeptide identified as CPN100638) for prosecution. The claims readable on the elected invention are claims 1-39, as amended above.

Applicants reserve all rights in the non-elected claims, including the right to file one or more divisional applications covering the subject matter thereof.

Applicants have elected SEQ ID NOs: 5, 6 and 14 (CPN100638) as a distinct invention for prosecution in the subject application. SEQ ID NO: 14 is the amino acid sequence. SEQ ID NO: 6 is a nucleic acid sequence encoding SEQ ID NO: 14.

The Examiner has alleged that the claims of Groups 11-20 do not relate to a single inventive concept under PCT Rule 13.1. Applicants respectfully disagree.

The Examiner is advised that the claims as amended are entitled to priority (US 60/110,339 filed on December 1, 1998). The claims as amended are fully supported by priority Application No. 60/110,339, specifically at Figures 1 and 2, which disclose SEQ ID NOs: 5, 6 and 14.

The Examiner's attention is directed to the Information Disclosure Statement filed concurrently with this response, disclosing an NCBI BLAST search. As indicated by the BLAST search results, SEQ ID No: 14 and fragments comprising at least 12 consecutive amino acids thereof, are novel.

A. The DNA and the polypeptide have the same essential structural element

Applicants maintain that the polypeptide of SEQ ID No: 14 and a nucleic acid encoding it constitute a single inventive concept. Annex B of the Administrative Instructions Under the PCT describes three particular situations for which the method for determining unity of invention contained in Rule 13.2 is explained in detail. One particular situation describes the relationship between intermediate and final products, as follows:

> (g) Intermediate and Final Product. The situation involving intermediate and final products is also governed by Rule 13.2.
>
> (i) The term "intermediate" is intended to mean intermediate or starting products. Such products have the ability to be used to produce final products having the ability to be used to produce final products through a physical or chemical change in which the intermediate loses its identity.

(ii) Unity of invention shall be considered to be present in the context of intermediate and final products where the following two conditions are fulfilled:

(A) the intermediate and final products have the same essential structural elements, in that:

(1) the basic chemical structures of the intermediate and the final products are the same, or

(2) the chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential structural element into the final product, and

(B) the intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same essential structural element.

A nucleic acid and the polypeptide it encodes are starting products and final products. There is unity because the DNA and the polypeptide have the same essential structural element, namely that both products share the same polymeric sequence. While nucleic acids and polypeptides are chemically different, the claimed nucleic acids and polypeptides share the same sequence structure, since the initiator codon is described and the nucleic acid sequence is understood to be read in triplets.

Applicants draw the Examiner's attention to part (f)(ii) of the Administrative Instructions, which states that "the structural element may be a single component or a combination of individual components linked together".

B. Example 17 of Annex B states that there is unity between protein and DNA

The Examiner is directed to Example 17 of Annex B of the Administrative Instructions Under the PCT. Example 17 states that there is unity between a claim to protein X and a claim to DNA sequence encoding protein X because the protein and the DNA sequence exhibit corresponding special technical features.

In consideration of the above, Applicants submit that the claims of Group 11 (claims 1-19, 25 and 38(a)) and Group 12 (claims 20-24, 27-34 and 38(b)) should be joined.

C. The polypeptide and its corresponding antibody share a special technical feature

The Examiner is directed to Example 8 of Annex B of the Administrative Instructions Under the PCT. Example 8 states that there is a special technical feature included in a claim to a plug characterized by feature A and a claim to a socket characterized by corresponding feature A, and that there is unity between these claims. The correspondence between a plug and its socket is equivalent to the correspondence between a protein and an antibody binding to it.

In consideration of the above, Applicants submit that the claims of Group 12 (claims 20-24, 27-34 and 38(b)) and Group 13 (claims 27, 35 and 38(c)) should be joined.

D. The protein/DNA and methods of using them share a special technical feature

The Examiner is directed to Example 1 of Annex B of the Administrative Instructions Under the PCT. Example 1 states that there is a special technical feature (substance X) between three categories of claims: (a) a claim to substance X; (b) a claim to a method of manufacturing substance X; and (c) a claim to the use of substance X, and states that the claims therefore have unity.

The claims of Groups 14, 15, 17, 18 and 20 (claims 36(a), 36 (b), 37(a), 37(b) and 39) are drawn to specific uses of the protein and DNA. The protein/DNA is the special technical feature between these claims and the claims of Groups 11 and 12. Applicants submit that the claims of Groups 14, 15, 17, 18 and 20 (claims 36(a), 36 (b), 37(a), 37(b) and 39), and the claims of Groups 11 and 12 (claims 1-24, 25, 27-34, 38(a) and 38(b)) should be joined.

E. The antibody and methods of using them share a special technical feature

The Examiner is directed to Example 1 of Annex B of the Administrative Instructions Under the PCT. Example 1 states that there is a special technical feature (substance X) between three categories of claims: (a) a claim to substance X; (b) a claim to a method of manufacturing substance X; and (c) a claim to the use of substance X, and states that the claims therefore have unity.

The claims of Groups 16 and 19 (claims 36(c) and 37(c)) are drawn to specific uses of the antibody. The protein to which the antibody is reactive is the special technical feature between these claims and the claims of Group 13. Applicants submit that the claims of Groups 16 and 19 (claims 36(c) and 37(c)), and the claims of Group 13 (claims 27, 35 and 38(c)) should be joined.

F. Burden of search

It is respectfully submitted that by this Amendment, the subject matter of the claims is sufficiently related that a thorough search of the subject matter of any one single independent claim would necessarily encompass a search for the subject matter of the remaining claims.

Thus, it is respectfully submitted that the search and examination of the entire application could be performed without serious burden. MPEP § 803 clearly states that "If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (emphasis added). It is respectfully submitted that this policy should apply in the present application in order to avoid unnecessary delay and expense to Applicants in duplicative examination by the Patent Office.

III. Concluding remarks

The Examiner is respectfully requested to reconsider and withdraw the Restriction Requirement and to examine claims 1-39, as amended, in this application.

If there are any fees due in connection with the filing of this Amendment, please charge the fees to Deposit Account No. 19-0741. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: June 26, 2003

Michele M. Simkin
Attorney for Applicant
Registration No. 34,717

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5109
Telephone: (202) 672-5427
Facsimile: (202) 672-5399

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. A nucleic acid molecule comprising a nucleic acid sequence which encodes a polypeptide selected from any one of:

(a) SEQ ID ~~Nos: 12 to 16;~~No: 14

(b) an immunogenic fragment comprising at least 12 consecutive amino acids from ~~a polypeptide of (a);~~SEQ 14; and

(c) a polypeptide of (a) or (b) which has been modified without loss of immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

2. A nucleic acid molecule comprising a nucleic acid sequence selected from any one of:

(a) SEQ ID ~~Nos: 3 to 10;~~No: 6;

(b) a sequence which encodes a polypeptide encoded by~~any one of~~ SEQ ID ~~Nos: 3 to 10;~~No: 6;

(c) a sequence comprising at least 38 consecutive nucleotides from any one of the nucleic acid sequences of (a) and (b); and

(d) a sequence which encodes a polypeptide which is at least 75% identical in amino acid sequence to ~~any one of the polypeptides~~the polypeptide encoded by SEQ ID ~~Nos: 3 to 10.~~No: 6.

4. A nucleic acid molecule comprising a nucleic acid sequence which encodes a fusion protein, said fusion protein comprising a first polypeptide and a second polypeptide, wherein the first polypeptide is selected from any one of:

(a) SEQ ID ~~Nos: 11-16;~~No: 14;

(b) an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of SEQ ID ~~Nos: 11-16;~~No: 14; and

(c) a polypeptide of (a) or (b) which has been modified without loss of immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

7. ~~A~~The nucleic acid molecule ~~according to~~of claim 1, operatively linked to one or more expression control sequences.

8. A vaccine comprising a vaccine vector and at least one first nucleic acid selected from any of:

(i) SEQ ID ~~Nos: 1 to 10;~~No: 6;

(ii) a nucleic acid sequence which encodes a polypeptide encoded by~~any one of~~ SEQ ID ~~Nos: 1 to 10;~~No: 14;

(iii) a nucleic acid sequence comprising at least 38 consecutive nucleotides from any one of the nucleic acid sequences of (i) and (ii);

(iv) a nucleic acid sequence which encodes a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by any one of SEQ ID ~~Nos: 1 to 10;~~No: 6;

(v) a nucleic acid sequence which encodes a polypeptide whose sequence is set forth in ~~any one of~~ SEQ ID ~~Nos: 11 to 16;~~No: 14;

(vi) a nucleic acid sequence which encodes an immunogenic fragment comprising at least 12 consecutive amino acids from~~any one of~~ SEQ ID ~~Nos: 11 to 16; and~~No: 14;

(vii) a nucleic acid sequence which encodes a polypeptide as defined in (i) to (v) or an immunogenic fragment as defined in (vi) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75%

identical in amino acid sequence to the corresponding polypeptide of (i) to (v) or the corresponding fragment of (vi);

wherein each first nucleic acid is capable of being expressed.

9. A vaccine comprising a vaccine vector and at least one first nucleic acid encoding a fusion protein, wherein the fusion protein comprises:

(a) a first polypeptide selected from any of:

(i) a polypeptide encoded by ~~any one of~~ SEQ ID ~~Nos: 1 to 10;~~No: 6;

(ii) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from ~~any one of~~ SEQ ID ~~Nos: 1 to 10;~~No: 6;

(iii) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by ~~any one of~~ SEQ ID ~~Nos: 1 to 10;~~No: 6;

(iv) a polypeptide whose sequence is set forth in ~~any one of~~ SEQ ID ~~Nos: 11 to 16;~~No: 14;

(v) an immunogenic fragment comprising at least 12 consecutive amino acids from ~~any one of~~ SEQ ID ~~Nos: 11 to 16;~~No: 14; and

(vi) a polypeptide as defined in (i) to (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (iv) or the corresponding fragment of (v); and

(b) a second polypeptide;

wherein each first nucleic acid is capable of being expressed.

13. ~~A vaccine according to~~The vaccine of claim 8 wherein each first nucleic acid is expressed as a polypeptide, and wherein the vaccine comprises a second nucleic acid encoding an additional polypeptide which enhances the immune response to the polypeptide expressed by the first nucleic acid.

15. A pharmaceutical composition comprising ~~a~~the nucleic acid ~~according to~~of claim 1 and a pharmaceutically acceptable carrier.

16. A pharmaceutical composition comprising ~~a~~the vaccine ~~according to~~of claim 8 and a pharmaceutically acceptable carrier.

18. An isolated nucleic acid probe of 5 to 100 nucleotides which hybridizes under stringent conditions to the nucleic acid molecule of~~any one of~~ SEQ ID ~~Nos: 3 to 10,~~No: 6, or to a complementary or anti-sense sequence of said nucleic acid molecule.

19. An isolated primer of 10 to 40 nucleotides which hybridizes under stringent conditions to the nucleic acid molecules of~~any one of~~ SEQ ID ~~Nos: 3 to 10,~~No: 6, or to a complementary or anti-sense sequence of said nucleic acid molecule.

20. A polypeptide encoded by ~~a~~the nucleic acid sequence ~~according to~~of claim 2.

21. A polypeptide comprising an amino acid sequence selected from any of:

(a) SEQ ID ~~Nos: 12 to 16;~~No: 14;

(b) an immunogenic fragment comprising at least 12 consecutive amino acids from ~~a polypeptide of (a);~~SEQ 14; and

(c) a polypeptide of (a) or (b) which has been modified without loss of immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

22. A fusion polypeptide comprising a first polypeptide and a second polypeptide, wherein the first polypeptide is selected from any one of:

(a) a polypeptide encoded by~~any one of~~ SEQ ID ~~Nos: 1 to 10;~~No: 6;

(b) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from~~any one of~~ SEQ ID ~~Nos: 1 to 10;~~No: 6;

(c) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by~~any one of~~ SEQ ID ~~Nos: 1 to 10;~~No: 6;

(d) a polypeptide whose sequence is set forth in~~any one of~~ SEQ ID ~~Nos: 11 to 16;~~No: 14;

(e) an immunogenic fragment comprising at least 12 consecutive amino acids from~~any one of~~ SEQ ID ~~Nos: 11 to 16;~~No: 14; and

(f) a polypeptide as defined in (a) to (d) or an immunogenic fragment as defined in (e) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) to (d) or the corresponding fragment of (e).

25. A method for producing ~~a~~the polypeptide of claim 20, comprising the step of culturing a unicellular host transformed with a nucleic acid encoding ~~a~~the polypeptide of claim 20.

27. A vaccine comprising at least one first polypeptide selected from any of:

(i) a polypeptide encoded by~~any one of~~ SEQ ID ~~Nos: 1 to 10;~~No: 6;

(ii) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from~~any one of~~ SEQ ID ~~Nos: 1 to 10;~~No: 6;

(iii) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by~~any one of~~ SEQ ID ~~Nos: 1 to 10;~~No: 6;

(iv) a polypeptide whose sequence is set forth in~~any one of~~ SEQ ID ~~Nos: 11 to 16;~~No: 14;

(v) an immunogenic fragment comprising at least 12 consecutive amino acids from~~any one of~~ SEQ ID ~~Nos: 11 to 16;~~No: 14; and

(vi) a polypeptide as defined in (i) to (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (iv) or the corresponding fragment of (v).

28. A vaccine comprising at least one fusion protein, wherein the fusion protein comprises:

(a) a first polypeptide selected from any of:

(i) a polypeptide encoded by SEQ ID No: ~~1;~~6;

(ii) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from SEQ ID No: ~~1;~~6;

(iii) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by SEQ ID No: ~~1;~~6;

(iv) a polypeptide whose sequence is set forth in SEQ ID No: ~~2;~~14;

(v) an immunogenic fragment comprising at least 12 consecutive amino acids from SEQ ID ~~No:2;~~No: 14; and

(vi) a polypeptide as defined in (i) to (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (iv) or the corresponding fragment of (v); and

(b) a second polypeptide.

33. A pharmaceutical composition comprising ~~a~~the polypeptide ~~according to~~of claim 20 and a pharmaceutically acceptable carrier.

34. A pharmaceutical composition comprising ~~a~~the vaccine ~~according to~~of claim 27 and a pharmaceutically acceptable carrier.

35. A pharmaceutical composition comprising ~~an~~the antibody ~~according to~~of claim 26 and a pharmaceutically acceptable carrier.

36. A method for preventing or treating *Chlamydia* infection comprising administering to a patient an effective amount of:

(a) ~~a~~the nucleic acid ~~according to~~of claim 2;

(b) a vaccine comprising a vaccine vector and at least one first nucleic acid ~~according to~~of claim 2;

(c) a pharmaceutical composition comprising ~~a~~the nucleic acid ~~according to~~of claim 2 and a pharmaceutically acceptable carrier;

(d) a polypeptide encoded by ~~a~~the nucleic acid ~~according to~~of claim 2; or

(e) an antibody against a polypeptide encoded by a nucleic acid ~~according to~~of claim 2.

37. A method of detecting *Chlamydia* infection comprising the step of contacting a body fluid of a mammal to be tested, with a component selected from any one of:

(a) ~~a~~the nucleic acid according to claim 2;

(b) a polypeptide encoded by ~~a~~the nucleic acid ~~according to~~of claim 2; and

(c) an antibody against a polypeptide encoded by ~~a~~the nucleic acid ~~according to~~of claim 2.

38. A diagnostic kit comprising instructions for use and a component selected from any one of:

(a) ~~a~~the nucleic acid according to claim 2;

(b) a polypeptide encoded by ~~a~~the nucleic acid ~~according to~~of claim 2; and

(c) an antibody against a polypeptide encoded by ~~a~~the nucleic acid ~~according to~~of claim 2.

39. A method for identifying ~~a~~the polypeptide of claim 20 which induces an immune response effective to prevent or lessen the severity of *Chlamydia* infection in a mammal previously immunized with polypeptide, comprising the steps of:

(a) immunizing a mouse with the polypeptide of claim 20; and

(b) inoculating the immunized mouse with *Chlamydia;*

wherein the polypeptide which prevents or lessens the severity of *Chlamydia* infection in the immunized mouse compared to a non-immunized control mouse is identified.